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For	:	SUTURE METHOD	

Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

DECLARATION OF DR. GREGORY L. RUFF

I, Dr. Gregory L. Ruff, declare as follows:

1. I am a United States citizen and my domicile address is 113 Campbell Lane, Chapel Hill, NC 27514.
2. I am an inventor on several patents and pending patent applications describing barbed tissue connectors and sutures, along with their uses. A list of these patents and published pending applications is set forth in Exhibit A.
3. I received an M.D. from the University of Michigan in Ann Arbor in 1978. I completed a general surgical residency at St. Joseph Mercy Hospital in Ann Arbor from 1978 to 1983, and from 1983 to 1986 I completed a residency in plastic surgery at Duke University Medical Center. In 1986, I joined Duke University Medical Center as an Assistant Professor in the Department of Surgery. In August of 2001, I had to cease surgical practice as a result of injuries suffered in an accident. In November of 2002, I left Duke University Medical Center to start my private clinical practice, which I maintain today, and I resumed surgical practice in December of 2002.

4. I am also a founder of Quill Medical, Inc., which is the assignee of those patents and patent applications on which I am an inventor of barbed tissue connectors and sutures (Exhibit A). Originally founded as Dermagraphics, Inc., Quill Medical, Inc., was formally organized into its present form as a Delaware corporation in December, 2000. I have been a consultant to Quill Medical, Inc., or its predecessors since February 14, 2000.

5. The first time I treated patients using prototype barbed sutures was in June of 1993 at Duke University Medical Center, and I continued to treat patients there using such prototype barbed sutures until the spring of 2001. To my best recollection, I treated 14 patients in 16 procedures during the period between June, 1993 and spring of 2001, using about 35 prototype barbed sutures.

6. For patients treated between June, 1993, and January, 2000, I made prototype barbed sutures by hand in the operating room just prior to treating the patient. These hand-made barbed sutures were prepared by taking commercially available sterile sutures such as Maxon or PDS-II having a curved needle at one end, and cutting a number of barbs into each suture using a sterile scalpel in a sterile field. The cutting was done using clamps to secure the plain suture to a surgical tray. My intention was to cut barbs into the suture at longitudinally spaced intervals to produce a rough helical pattern of barbs along the length of the suture. Multiple barbs facing one end of the suture were cut along a length of the suture, and then the suture was turned slightly on the surgical pan for another series of cuts. The imprecision of the hand-cutting technique, however, likely created a random pattern, and no measurements were taken nor or optical magnification used to determine the uniformity or precision of the cut barbs. Barbs were cut in the suture to obtain a bi-directional arrangement of separate groups of barbs on each suture.

7. Once made, a prototype barbed suture was placed into a patient by first straightening out the curved needle, which was already attached to the suture, in order to insert the needle end and one part of the bi-directional suture into the patient's tissue. To insert the other end of the suture, either a single "eyelet" needle was attached to the free end of the suture and inserted into the patient, or a trocar was passed through the tissue to the entrance point and the remainder of the barbed suture passed into the trocar which was then removed.

8. Beginning in November, 2000, until spring, 2001, several patients were treated with prototype barbed sutures made from commercially available sutures (size 0 PDS from Ethicon) that were cut with a precision, manually-operated, fabrication device designed, constructed by, and obtained under an agreement with, Quill Medical, Inc. (see Exhibit B). This device permitted multiple barbs to be cut at a single time, and allowed the suture to be turned approximately 120 degrees for another series of cuts which were offset longitudinally in order to achieve a helical array in the final prototype barbed suture. Sutures with a bi-directional arrangement of barbs were made with the manual device, and a second needle was swaged onto the free end of the suture. I was also under an obligation of confidentiality with Quill Medical, Inc., during this period as a consequence of my confidentiality and inventions agreement with the Company (see Exhibit C).

9. The patients treated with prototype barbed sutures during the period from June, 1993, until spring, 2001, were treated in a variety of ways to rearrange intact tissue as well as in the closure of cutaneous and deeper wounds. These procedures included: correction of severe ectropion of the ispilateral lower eyelid; shortening of the vertical dimension of the upper lip; symmetrical positioning of the inframammary fold in association with placement of a breast protheses; closure of a wound from an excisional biopsy; and correction of ptotic brows, necks and cheeks.

10. Following each of the surgical procedures described above, I performed at least one follow-up visit with the patient to determine the effectiveness of the prototype barbed sutures and the cosmetic results using such sutures in the different surgical procedures, as well as to observe the durability of the sutures. For a majority of patients, I also had additional follow-up visits to further observe the effectiveness and durability of the barbed suture prototypes. A detailed description for these patients and their treatment follows in the subsequent paragraphs. A summary of the treatment and outcomes for most of these patients is summarized in the attached Exhibit D.

11. In June of 1993, I treated a patient with a deformity attributable to a gun shot wound by supporting the elevation of the left side of the patient's mouth with a prototype barbed

suture using a needle for placing one end of the suture and a trocar for placement of the other end of the suture.

12. In December of 1993, I treated an otherwise healthy male in his early thirties who felt his upper lip covered too much of his upper teeth when he smiled and therefore desired shortening of the vertical dimension of his lip without an external scar. One prototype barbed suture was placed on either side of his upper lip extending vertically from the vermilion of the lip to the base of the nose with the transition point midway along the suture. A modest improvement was seen on the operating table which slowly regressed as I followed his progress over several months. There was no undue tissue reaction from the suture despite the highly mobile nature of this portion of the face.

13. In December of 1993, I treated an otherwise healthy woman in her early twenties who sustained an abrasion of her right malar eminence which extended down into the superficial aspect of the bone. A tissue expander was used inferior to the defect to create new skin; however, the resulting scar contracture caused a severe ectropion of the ipsilateral lower eyelid. This necessitated at least three other procedures to elevate and tighten the lower lid. In three of these procedures, a prototype barbed suture was used to help reduce the tendency of the lower lid to retract about its lateral aspect. The transition point of the prototype barbed suture, at which the barbs change direction, was inferior to the lateral canthal tendon and extended medially under the lower eyelid and laterally toward the temple. To avoid compromise of the zygomatic branches of the facial nerve, the prototype barbed suture was placed very superficially within the attenuated expanded skin. In one instance, this was well tolerated and spontaneously resorbed while in the other, a portion of the suture became exposed and it was removed due to subsequent inflammation. It was felt that the prototype barbed suture contributed to the success of the lower lid reconstruction in each instance.

14. In December of 1993, I also treated a woman with a prototype barbed suture in an attempt to correct a scar on her upper lip.

15. In February of 1994, I treated a child with prototype barbed sutures in an attempt to narrow a web of skin located between her eyes. I placed a prototype barbed suture across the upper bridge of her nose.

16. In August of 1995, I treated a young man with a lower eyelid lesion, using a prototype barbed suture to close the lesion.

17. At approximately the same time as treating the patients described in paragraphs 14-16, above, I also used a prototype barbed suture in an adult to close the wound resulting from a small excisional biopsy of a cutaneous lesion extending down into the subcutaneous tissue. The single prototype barbed suture utilized measured approximately 3 cm in length and was placed in the superficial subcutaneum just deep to the reticular dermis at right angles to the incision with its transition point at the incision. Standard skin sutures were used to close the outer portion of the incision and the wound healed uneventfully. The alternative to the prototype barbed suture would have been an inverted interrupted 3-0 or 4-0 Vicryl suture knotted conventionally.

18. The prototype barbed suture was also utilized in an otherwise healthy woman in her mid-twenties who underwent bilateral breast augmentation utilizing an axillary incision with subpectoral placement of the breast prostheses in May of 1998. Post-operatively, her right inframammary fold was inferiorly displaced and she refused correction with an inframammary incision as was recommended. Accordingly, the axilla was reopened, the prostheses removed and utilizing a fiberoptic scope, prototype barbed sutures were placed percutaneously through the chest wall superficial to the pocket surrounding the prosthesis. The swaged-on needle was introduced first and it, along with the antegrade barbed portion of the prototype barbed suture, were passed through the pocket and into posterior aspect of the capsular scar and periosteum of the rib. The retrograde barbed segment was sheathed in a 16-gauge hypodermic needle which was withdrawn once this portion of the prototype barbed suture entered the anterior chest wall. The transition point therefore lay within the compressed pocket which was effectively closed off at this level by snugging down the anterior chest wall. Four of these prototype barbed sutures were used after which the breast prosthesis was replaced and the axillary wound closed. The inframammary fold was thereby restored to a symmetrical position and the patient recovered uneventfully utilizing compression from her support garments to help maintain the fold at this level. Thus, four prototype barbed sutures effectively closed the inferior portion of the prosthetic pocket without utilizing any conventional sutures.

19. In January of 2000, a prototype barbed suture was utilized in a healthy 34 year-old man with a ptotic brow. One prototype barbed suture was used in a vertical fashion about each side of the forehead extending superiorly from the junction of the middle and lateral third of the eyebrow with its transition point just inferior to the hairline. It was placed at a depth midway between the skin and frontalis muscle. The brow was elevated 6 mm bilaterally and follow-up in 17 months revealed that the lift had relaxed somewhat but that there still appeared to be partial correction of his ptosis. This type of brow lift was used in three other healthy women 34, 58 and 59 years old. One prototype barbed suture was used only on the right side of the two younger patients. Treatment of the 58 and 59 year old women is discussed in paragraph 21 below.

20. In November of 2000, I used for the first time prototype barbed sutures made using the precision, manually-operated, fabrication device from Quill to treat a patient. I treated a 53 year-old patient concerned about aging changes of her neck and upper cheeks by placing prototype barbed sutures in these locations. Her neck was treated as described for the patient in paragraph 22, below, while the transition point for the prototype barbed sutures of this patient's upper cheeks was at the anterior margin of her hairline at the level of the eye.

21. Subsequent to November, 2000, but before spring, 2001, I used prototype barbed sutures placed as described above in paragraph 19, but in the 58 year-old patient in that it was placed deep to the frontalis muscle, in an attempt to minimize its palpability. While both patients tolerated the prototype barbed suture placement well post-operatively, the older patient had recurrence of the brow ptosis within two months which may have been due to its depth. She had noticed some pulling and 'snapping' sensations when she raised and lowered her right eyebrow. The location of the prototype barbed suture in the loose plane over which the forehead moves may have deflected the barbs causing these feelings which subsided in 4-6 weeks. The 59 year-old patient's ptotic brows were lifted with two prototype barbed sutures on each side combined with a chemical peel of her forehead. Ongoing follow-up shows no untoward suture reaction and residual correction at two months.

22. Also subsequent to November, 2000, but before spring, 2001, I used a prototype barbed suture placed in an otherwise healthy 60 year-old woman concerned about laxity of the skin of her neck and lower cheeks. The sutures were placed in a linear fashion bilaterally in each of these areas with the transition point of the suture overlying the sternomastoid muscle and posterior cheek, respectively. The portion of the prototype barbed suture posterior to this point was approximately 3 cm while the portion of the barbed suture anterior to this point measured approximately 8 cm.

23. All of the prototype barbed sutures placed in the cheeks and necks of patients described in paragraphs 22 and 20 were in the subcutaneous plane and all resulted in excellent immediate correction of the skin laxity in these regions. However, the ends of the sutures in each patient's neck and those in the younger patient's upper cheeks, became prominent about their medial ends in the period from one to three weeks post placement. These were subsequently removed under local anesthesia and the portion of the suture that was recovered contained barbs in one direction only suggesting that they broke at their transition point. Evaluation of extra sutures manufactured simultaneously with those placed in these patients revealed that the barbs cut at opposing directions overlapped at the transition point, thereby weakening the suture at this juncture. The cutting blades of the fabrication device were adjusted to correct this problem and the prototype barbed sutures above the neck and upper cheeks of the younger patient were replaced and well tolerated with improvement lasting at least three months post-operatively.

24. The patients described above were generally informed that they were being treated with conventional sutures modified by barbing of the suture filament. The surgical assistants in the operating room also had general knowledge of the prototype barbed sutures. Reconstructive patients were usually under general anesthesia, whereas the patients being treated cosmetically were under either general or local anesthesia depending on the case. All patient medical records were under obligations of confidentiality pursuant to the policies of Duke University Medical Center.

25. A summary of my experience with prototype barbed sutures as set forth above was submitted by Quill Medical, Inc., to the Food and Drug Administration as part of a 510(k) application for clearance of a "PDS II Synthetic Absorbable Surgical Suture." This

510(k) application was submitted on October 16, 2001, and was decided on October 26, 2004. A copy of this summary is attached as Exhibit E.

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements, and the like so made, are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Gregory Piaff MD

Date: August 19, 2005